
# CTMS Lab Interfaces SIG Teleconference
# Meeting Minutes

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| **Meeting Date** | August 5, 2004<br>4-5 PM EDT |
| **Attendees:** | **Working group coordinator**: Scott Finley (Booz Allen Hamilton)<br>Harshawardhan Bal (Booz Allen Hamilton)<br><br>**Participants:** |

| Name | Email | Organization |
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| **John Speakman (SIG Lead)** | **speakman@biost.mskcc.org** | **Memorial Sloan-Kettering Cancer Center** |
| Jieping Li | lj38@georgetown.edu | Georgetown |
| Christo Andonyadis | andonyac@mail.nih.gov | NCI |
| Deborah Collyar | collyar@att.net | PAIR |
| Donald Connelly | don@umn.edu | U. Minnesota |
| Rebecca Boes | boesr@msx.upmc.edu | UPMC |
| Sorena Nadaf | s.nadaf@vanderbilt.edu | Vanderbilt |
| Brenda Duggan | dugganb@mail.nih.gov | NCICB |
| Charles Lu | charles.lu@yale.edu | Yale |

**Agenda**

- Review of decisions made at face-to-face-meeting
  - The model is to import as much lab data as possible on the way into the CTMS, and filter on the way out
  - Should it become obvious that HL7 v2.x-to-v3 adapters are necessary, we will use Sunquest and Cerner as use cases
  - Some means of producing a “clinical systems best practices” white paper is probably necessary – not necessarily a SIG
- Review of action items
  - Find out ETA from Sunquest/Cerner when they plan to implement HL7v3
  - Research how MSKCC handles the patient privacy implications of holding all the patient’s lab data from registration time forever
  - Attempt to obtain lab data flow diagrams from other

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| | institutions<br><br>• Schedule for future conference calls |
| **General discussion points raised by participants:** | Specific areas that were discussed were as follows:<br><br>• Expiration date for patient data collection (Duration for which patient data can be collected and whether each study had a specific expiration date or event). While the research authorization document contains a placeholder for an expiration date or event, it can be "none", in which case, patients can be followed indefinitely even if they are no longer on a protocol. The concern for investigators is that clinical research would be harmed if patients could only be followed for a limited time and therefore be deprived of important research findings and adverse events that may take longer than the study duration to surface. On the other hand, whether this was HIPAA compliant needs to be determined. If this was not permissible under HIPAA, the consent may need to be refreshed for the appropriate period.<br><br>• Types of tests that can be performed or types of data that can be collected: It was not clear if laboratory tests performed or data collected from a patient were restricted to what was necessary for the specific protocol under which the patient was enrolled or if it could be extended to other tests and data not directly relevant to the protocol in question. Tests not tied to the research hypothesis may not be allowed. Again, interpretation of the relevant HIPAA rules was necessary.<br><br>• HIPAA/IRB related issues: Deborah Collyar suggested that members of the Lab Interfaces SIG attend the 2004 Annual Institutional Review Board Conference (October 28-31, 2004, San Diego, CA) (http://www.primr.org/education/2004_IRB/overview.html), organized by PRIM&R (http://www.primr.org/) whose mission is to create, implement and advance the highest ethical standards in the conduct of research, as a means to get answers to common HIPAA/IRB related issues.<br><br>• Obtaining tissue consent: It was suggested that as part of the informed consent process, the consent to obtain tissue samples from study subjects be obtained at the outset so that appropriate specimens can be obtained and tracked. |

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| | • Software issues: The different centers such as Yale, Minnesota, Georgetown and Vanderbilt would share existing work flows or functional diagrams for their respective Lab Interfaces with John who would then create a list of database tables, entity relationship diagrams (ERD) and SOWs for software based on caBIG principles. |
| **Action items:** | 1. Attempt to obtain lab data flow diagrams from other institutions<br><br>2. Create a list of database tables, ERDs and requirements that can be used as the basis for an SOW for caBIG's lab interface module<br><br>3. Assemble a list of topics to be covered in a clinical and research systems best practices white paper, addressing IRB/HIPAA etc. |